

## Part VI: Summary of the risk management plan

### Summary of risk management plan for

#### Levetiracetam Kalceks

(levetiracetam)

This is a summary of the risk management plan (RMP) for Levetiracetam Kalceks. The RMP details important risks of Levetiracetam Kalceks, how these risks can be minimised, and how more information will be obtained about Levetiracetam Kalceks risks and uncertainties (missing information).

Levetiracetam Kalceks's summary of product characteristics (SPC) of Levetiracetam Kalceks and its package leaflet give essential information to healthcare professionals and patients on how Levetiracetam Kalceks should be used.

Important new concerns or changes to the current ones will be included in updates of Levetiracetam Kalceks's RMP.

#### I. The medicine and what it is used for

Levetiracetam Kalceks is authorised for monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adults and adolescents and adolescents from 16 years of age with newly diagnosed epilepsy. Also, Levetiracetam Kalceks is authorised for adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy; in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy; in the treatment of primary generalised tonic clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy (see SmPC for the full indication). It contains levetiracetam as the active substance and it is given via intravenous route of administration.

#### II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Levetiracetam Kalceks, together with measures to minimise such risks and the proposed studies for learning more about risks of Levetiracetam Kalceks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size – the amount of medicine in a pack is chosen so to

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- ensure that the medicine is used correctly;
- The medicine's legal status – the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Levetiracetam Kalceks is not yet available, it is listed under "missing information" below.

#### ***II.A List of important risks and missing information***

Important risks of Levetiracetam Kalceks are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Levetiracetam Kalceks. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

<b>Summary of safety concerns</b>	
<b>Important identified risks</b>	<i>None</i>
<b>Important potential risks</b>	<i>None</i>
<b>Missing information</b>	<i>Long-term effects on learning, intelligence, growth, endocrine function, puberty, and childbearing potential in children with epilepsy or in children exposed in utero</i>

#### ***II.B Summary of important risks***

The safety information in the proposed Product Information is aligned to the newest knowledge.

#### ***II.C Post-authorisation development plan***

##### ***II.C.1 Studies which are conditions of the marketing authorisation***

There are no studies which are conditions of the marketing authorisation or specific obligation of Levetiracetam Kalceks.

##### ***II.C.2 Other studies in post-authorisation development plan***

There are no studies required for Levetiracetam Kalceks.